

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
23 June 2005 (23.06.2005)

PCT

(10) International Publication Number
WO 2005/056419 A1

(51) International Patent Classification⁷: **B65D 75/34**

(21) International Application Number:
PCT/GB2004/050036

(22) International Filing Date: 9 December 2004 (09.12.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0328614.3 10 December 2003 (10.12.2003) GB
0409717.6 30 April 2004 (30.04.2004) GB

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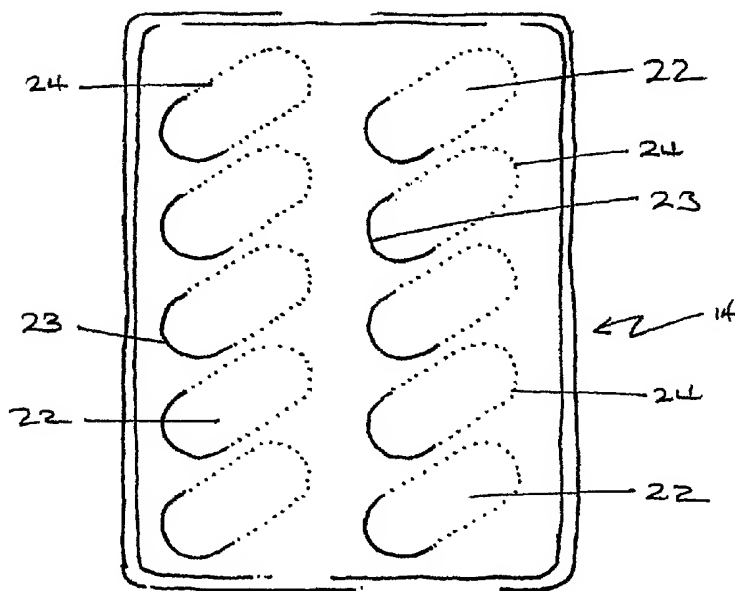
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,

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(54) Title: IMPROVEMENTS IN OR RELATING TO BLISTER PACKS



(57) Abstract: The present invention relates to a medicament retaining sheet (14) for a medicament blister pack. In particular, it relates to a medicament retaining sheet which makes it more difficult for a child to release a medicament from the blister pack without making it unduly difficult for the elderly or infirm to remove the medicament. We describe a medicament blister pack retaining sheet (14) comprising at least one sheet (20) having points of weakness (23, 24) defining medicament release zones.

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SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, — *with amended claims*
GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

IMPROVEMENTS IN OR RELATING TO BLISTER PACKS

The present invention relates to improvements in or relating to blister packs. In particular, it relates to an improvement in blister packs which makes it more difficult for a child to release a medicament from the blister pack without making it unduly difficult for the elderly or infirm to remove the medicament.

Conventional blister cards or packs typically include a plastics sheet material moulded to provide a plurality of recesses into each of which recesses is placed a medicament, typically in tablet or capsule form. The medicaments are held in place by means of a foil retaining sheet. When the patient wishes to use the medicament, they push the tablet or capsule through the foil retaining sheet. For ease of release, the foil retaining sheet is usually rather thin and easily ruptured. This raises issues of child safety, as it becomes very easy for a child to tamper with the blister pack, so releasing the medication. One approach to improving the child-resistance of a blister pack is to increase the thickness of the foil in order to require greater strength in order to push the medicament through the foil retaining sheet. However, one needs to be careful to avoid producing a blister pack from which elderly or infirm might find it impossible to gain access to their medicament.

Accordingly, there is a need to provide a blister pack that provides resistance to tampering by children but allows the elderly or infirm to release their medicament without undue difficulty. WO 02/32666 describes one approach in which a first sheet material is attached to the foil of a conventional blister pack by a temporary adhesive. The first sheet covers all of the individual medicament recesses, but is itself of smaller overall dimensions than the blister pack itself. Overlaying the first sheet is a second sheet material. This is provided with a permanent adhesive and is larger than the first sheet material such that where it overlies the first sheet, it is adhered thereto by the permanent adhesive, but where it does not overlie the

first sheet, it adheres by the permanent adhesive to the foil retaining sheet of the blister pack. The second sheet is perforated or scored in the area around where it overlies each medicament recess. The user peels off a portion of the second sheet adjacent the location of a medicament. The perforations ensure selective removal
5 only of that part adjacent the chosen medicament and the use of a permanent adhesive provides that a respective portion of the first sheet material is also removed. The user can then press the medicament through the foil layer as usual.

However, the arrangement of WO 02/32666 requires careful cutting and assembly
10 of the components. The present invention seeks to provide an alternative blister pack arrangement.

In its broadest sense, in one aspect the present invention provides a medicament blister pack comprising a medicament tray having an upper surface to which is
15 bonded a medicament retaining sheet. The medicament retaining sheet comprises a laminate comprising bonded first and second sheet materials.

Preferably, the medicament tray comprises a moulded plastics or metallised tray having a plurality of individual medicament receiving cavities. Suitably, the tray
20 is formed by vacuum moulding.

Preferably, the first sheet material includes lines of weakness defining medicament release zones, or includes a random or structured pattern of lines of weakness having a substantially uniform distribution over the first sheet material.

Typically, the lines of weakness defining medicament release zones comprise perforations and/or slits. Suitably, the lines of weakness are formed by kiss-cutting or laser-cutting.
25

In a second aspect the present invention provides a medicament retaining sheet for a medicament blister pack, the retaining sheet comprising a laminate comprising bonded first and second sheet materials; said first sheet having first and second faces and said second sheet having first and second faces, wherein the first face of the second sheet and the second face of the first sheet are opposed and bonded together and wherein the first sheet includes lines of weakness defining medicament release zones.

In a third aspect, the present invention provides the use of a laminate comprising bonded first and second sheets as a medicament retaining sheet in a blister pack, wherein the first sheet includes lines of weakness defining medicament release zones.

The first sheet may be formed from any suitable material such as metal foil, metalised plastics, plastics, materials or paper. Preferably, the first sheet is a paper material. Suitably the paper material is a machine-coated or blade-coated paper.

Preferably, the first sheet has a weight of from 15 to 100 g/m²; more preferably from 20 to 50 g/m²; even more preferably about 30 g/m².

Preferably, the first sheet has a thickness of from 15 to 120µm; more preferably from 20 to 60µm; even more preferably about 30µm.

Preferably, the first sheet has first and second faces and lines of weakness may be formed partially in either the upper or lower surface or may extend from the first face through the sheet to the second face. Typically, the lines of weakness comprise perforations, slits or score lines, formed by kiss-cutting or laser-cutting.

Preferably, the second sheet material is a metal foil or a metalised plastics sheet. Preferably, the foil sheet is from 6 to 50µm in thickness.

Suitably, the first sheet material is bonded to the second sheet material by means of an adhesive, preferably a permanent adhesive.

Advantageously, no adhesive is provided, or the adhesive is inactivated, between
5 the first and second sheet materials in the medicament release zones.

In a fourth aspect, the present invention provides a first sheet material adapted for application to a medicament blister pack comprising a medicament tray having an upper surface to which is bonded a second sheet material.

10

Suitably, the first sheet is a printable material, such as paper or a synthetic material. Suitably the paper material is a machine-coated or blade-coated paper. Preferably, the paper has a weight of 20g/m^2 or more, more preferably from 50 to 400g/m^2 ; even more preferably from 50 to 200g/m^2 , most preferably from 50 to 150g/m^2 .

15

Advantageously, the paper has a weight of from 50 to 120g/m^2 , suitably about 80 to about 85g/m^2 .

The first sheet has first and second faces and lines of weakness may be formed partially in either the upper or lower surface or may extend from the first face through
20 the sheet to the second face. Typically, the lines of weakness comprise perforations, slits or score lines, formed by kiss-cutting or laser-cutting.

The above and other aspects of the present invention will now be illustrated in further detail, by way of example only, with reference to the accompanying figures in which:

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Figure 1 is a schematic sectional view of an embodiment of a blister pack in accordance with the present invention;

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Figure 2 is a plan view of the embodiment of Figure 1; and

Figures 3a-d are plan views of suitable alternative arrangements for points of weakness for embodiments of the present invention;

5

Referring to the figures, there is shown a blister pack 10 comprising a moulded plastics tray 11 including a plurality of moulded cavities or recesses 12 each containing a medicament in the form of a capsule or tablet 13. The tablets are held in place by means of a medicament retaining sheet 14. Retaining sheet 14 is
10 adhered to tray 11 by means of an adhesive 15.

Medicament retaining sheet 14 is a laminate comprising bonded first 20 and second 21 sheet materials. Suitably, the first sheet material 20 is a paper material. Suitably, the second sheet material 21 is a sheet material of the type
15 conventionally used in the production of blister packs. For example, the second sheet material 21 may be a thin metallic foil or a metalised plastics sheet material.

The medicament retaining sheet 14 is adhered to the tray 11 by adhesive 15 contacting second sheet material 21. The adhesive 15 may be applied to the
20 retaining sheet 14 or directly to the tray 11, for example by roller-coating.

The medicament retaining sheet 14 may be applied to the tray 11 during the manufacturing process. Alternatively, the first sheet material may be applied as a label to a pre-formed blister pack, for example, by an end user. The label may
25 include an adhesive surface for application to the foil of the blister pack. This forms another aspect of the present invention.

Figure 2 exemplifies a preferred formation of lines of weakness defining medicament release zones, of particular advantage in the embodiment described
30 above, where there is an absence of adhesive in said zones. In this preferred

embodiment, medicament release zones 22 are defined by lines of weakness comprising a cut or slit 23 at one end of each zone 22 with perforations 24 for completing the lines of weakness. With such an arrangement, it is easy for a user to rupture the medicament retaining sheet 14 at the end having slit 23 by pushing the tablet 13 at that end. The remainder of the first sheet material of the medicament release zone may then be peeled back.

Figure 3 shows, in views (a) to (e), a number of exemplary designs of points of weakness formed in labels and medicament retaining sheets of the present invention. The points take the form of simple regions of slits, as exemplified in Figures 3a & 3b in which lines of slits transverse the sheet horizontally and diagonally, respectively. Alternatively, the points comprise combinations of intersecting perpendicular lines of slits which transverse the sheet longitudinally and latitudinally, as illustrated in Figure 3c. In further alternative embodiments the intersecting lines are arranged diagonally (not shown). The points of weakness may alternatively take the form of repeating patterns such as crosses (Figure 3d). It will be appreciated that the lines of slits can be formed from uniformly sized slits as illustrated in Figures 3a to d, but may also be formed from slits of different lengths as exemplified in Figure 3e in which lines comprising slits of a first length perpendicularly intersect lines of slits of a second, different, length. Other arrangements will be immediately apparent to the skilled person. As shown, the distribution of points of weakness is uniform and regular. In alternative embodiments, the distribution may be irregular or random.

Claims:

1. A medicament retaining sheet for a medicament blister pack, said sheet comprising a first sheet having first and second faces and a second sheet having first and second faces, wherein the first face of the second sheet and the second face of the first sheet are opposed and bonded together and wherein the first sheet includes lines of weakness defining a plurality medicament release zones.

2. A medicament retaining sheet as claimed in Claim 1 wherein the lines of weakness defining medicament release zones comprise a plurality of perforations and/or slits.

3. A medicament retaining sheet as claimed in Claim 2 wherein the lines of weakness are formed in the first face of the first sheet.

4. A medicament retaining sheet as claimed in Claim 1 or Claim 2 wherein the lines of weakness extend from the first face of the first sheet, through the sheet and to the second face of said sheet in at least a portion of each individual medicament release zone.

5. A medicament retaining sheet as claimed in any one of claims 1 to 4 which comprises a laminate.

6. A medicament retaining sheet as claimed in any one of claims 1 to 5 wherein at least portions of the second face of the second sheet are provided with a permanent adhesive.

7. A medicament retaining sheet as claimed in Claim 5 wherein the second face of the second sheet is fully coated with a permanent adhesive.

8. A medicament retaining sheet as claimed in Claim 5 wherein the second face of the second sheet is provided with no permanent adhesive in the medicament release zones.

5 9. A medicament retaining sheet as claimed in any preceding claim wherein the second sheet is formed from a metal foil or a metalised plastics material.

10. A medicament retaining sheet as claimed in any preceding claim wherein the first sheet is formed from a paper material.

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11. A medicament retaining sheet as claimed in any one of the preceding claims for use in the manufacture of a medicament blister pack.

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12. The use of a medicament retaining sheet according to any one of the preceding claims in the manufacture of a medicament blister pack.

13. A medicament blister pack comprising a medicament retaining sheet according to any one of claims 1 to 10 above.

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14. A blister pack as claimed in Claim 13 wherein the medicament tray comprises a moulded plastics or metallised tray including a plurality of medicament cavities.

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15. A label for a medicament blister pack comprising a medicament tray having a plurality of moulded cavities or recesses each containing a medicant in the form of a capsule or tablet, said capsules or tablets being held in place by means of a *retaining sheet*, wherein said label has a first and second faces, said first face having an adhesive applied thereto and wherein said label includes lines of weakness defining a plurality of medicament release zones.

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16. A label as claimed in Claim 15 wherein the lines of weakness defining medicament release zones comprise a plurality of perforations and/or slits.

17. A label as claimed in Claim 15 or Claim 16 wherein the lines of weakness extend from the upper surface, through the label, to the lower surface of said label in at least a portion of each individual medicament release zone.

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18. A label as claimed in Claim 15 or Claim 16 wherein the lines of weakness are formed in the second face of the label.

19. A label as claimed in any one of Claims 15 to 18 wherein no adhesive is applied to the first face in the medicament release zones.

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AMENDED CLAIMS

[received by the International Bureau on 31 May 2005 (31.05.05),
original claims 1 to 19 replaced by new claims 1 to 22 (3 pages)]

1. A medicament retaining sheet for a medicament blister pack, said sheet comprising a first sheet having first and second faces and a second sheet having first and second faces, wherein the first face of the second sheet and the second face of the first sheet are opposed and bonded together and wherein the first sheet includes lines of weakness defining a plurality medicament release zones.
2. A medicament retaining sheet as claimed in Claim 1 wherein the lines of weakness defining medicament release zones comprise a plurality of perforations and/or slits.
3. A medicament retaining sheet as claimed in Claim 2 wherein the lines of weakness are formed in the first face of the first sheet.
4. A medicament retaining sheet as claimed in Claim 1 or Claim 2 wherein the lines of weakness extend from the first face of the first sheet, through the sheet and to the second face of said sheet in at least a portion of each individual medicament release zone.
5. A medicament retaining sheet as claimed in any one of claims 1 to 4 which comprises a laminate.
6. A medicament retaining sheet as claimed in any one of claims 1 to 5 wherein at least portions of the second face of the second sheet are provided with a permanent adhesive.
7. A medicament retaining sheet as claimed in Claim 5 wherein the second face of the second sheet is fully coated with a permanent adhesive.

AMENDED SHEET (ARTICLE 19)

8. A medicament retaining sheet as claimed in Claim 5 wherein the second face of the second sheet is provided with no permanent adhesive in the medicament release zones.
9. A medicament retaining sheet as claimed in any preceding claim wherein the second sheet is formed from a metal foil or a metalised plastics material.
10. A medicament retaining sheet as claimed in any preceding claim wherein the first sheet is formed from a paper material.
11. A medicament retaining sheet as claimed in any one of the preceding claims for use in the manufacture of a medicament blister pack.
12. The use of a medicament retaining sheet according to any one of the preceding claims in the manufacture of a medicament blister pack.
13. A medicament blister pack comprising a medicament retaining sheet according to any one of claims 1 to 10 above.
14. A blister pack as claimed in Claim 13 wherein the medicament tray comprises a moulded plastics or metallised tray including a plurality of medicament cavities.
15. A label for a medicament blister pack comprising a medicament tray having a plurality of moulded cavities or recesses each containing a medicant in the form of a capsule or tablet, said capsules or tablets being held in place by means of a retaining sheet, wherein said label has a first and second faces, said first face having an adhesive applied thereto and wherein said label includes lines of weakness defining a plurality of medicament release zones.
16. A label as claimed in Claim 15 wherein the lines of weakness defining medicament release zones comprise a plurality of perforations and/or slits.

17. A label as claimed in Claim 15 or Claim 16 wherein the lines of weakness extend from the upper surface, through the label, to the lower surface of said label in at least a portion of each individual medicament release zone.
18. A label as claimed in Claim 15 or Claim 16 wherein the lines of weakness are formed in the second face of the label.
19. A label as claimed in any one of claims 15 to 18 wherein at least portions of the second face of the second sheet are provided with a permanent adhesive.
20. A label as claimed in Claims 19 wherein no adhesive is applied to the first face in the medicament release zones.
21. A label as claimed in any one of Claims 15 to 18 wherein the first face is fully coated with a permanent adhesive.
22. A label as claimed in any one of Claims 15 to 21 wherein the label is formed from a paper material.

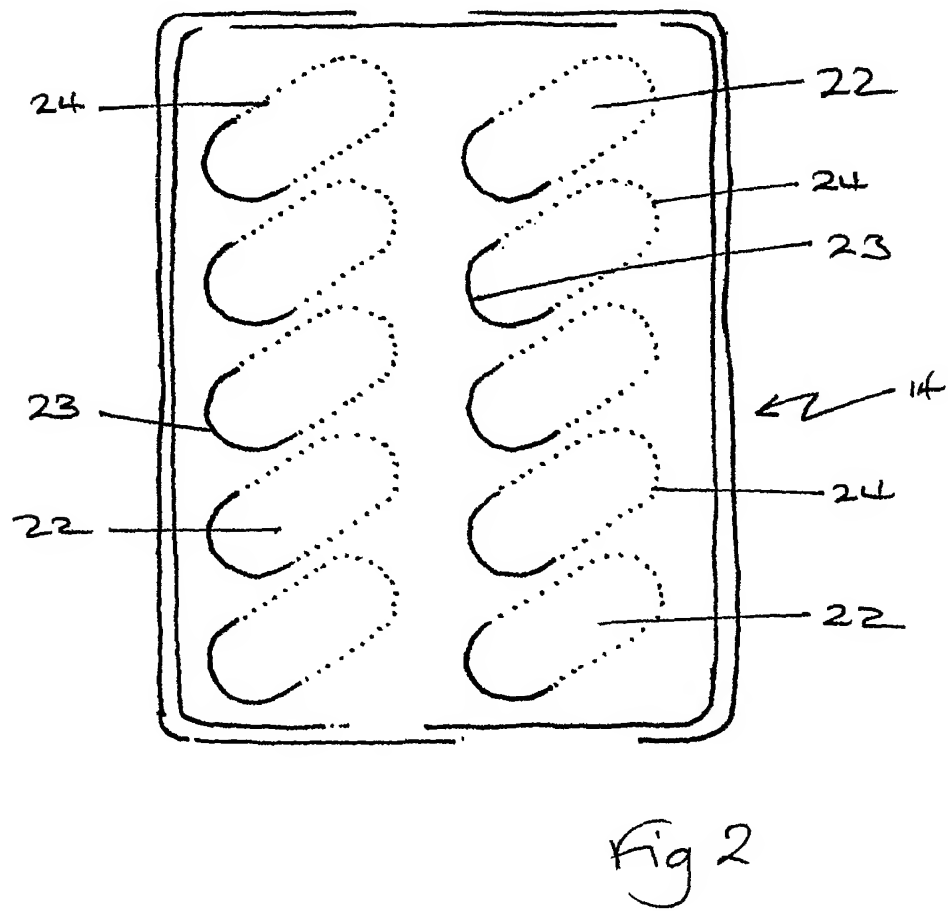
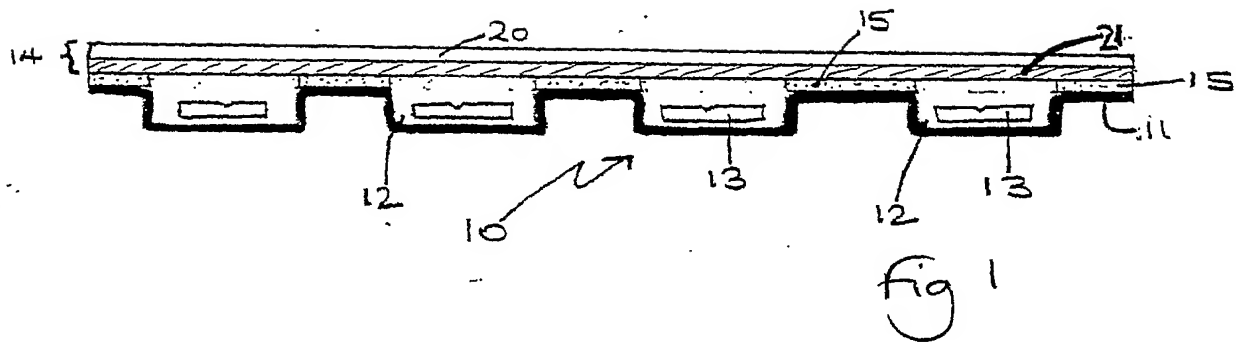


Figure 3A

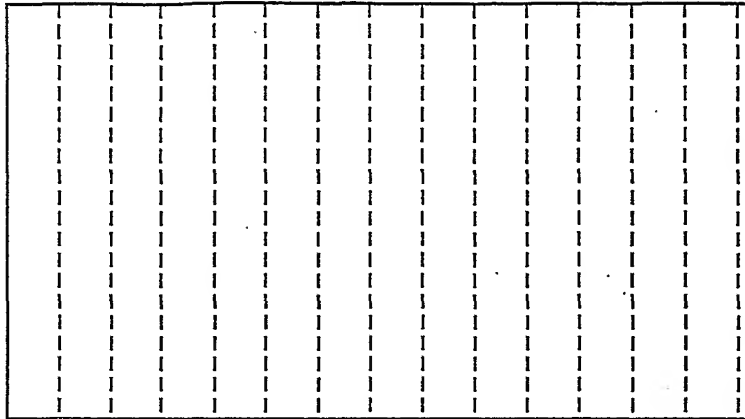


Figure 3B

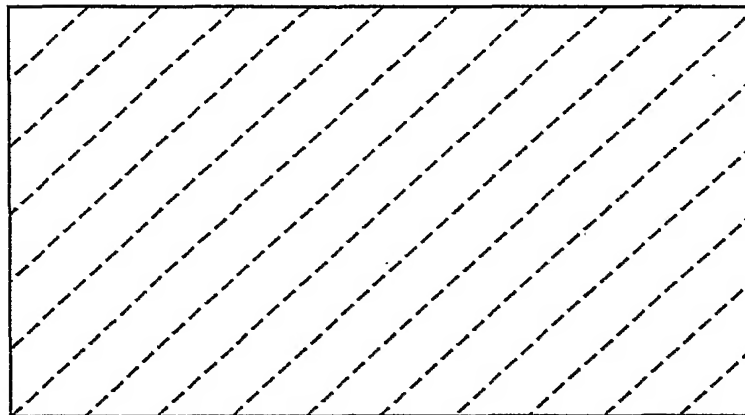


Figure 3C

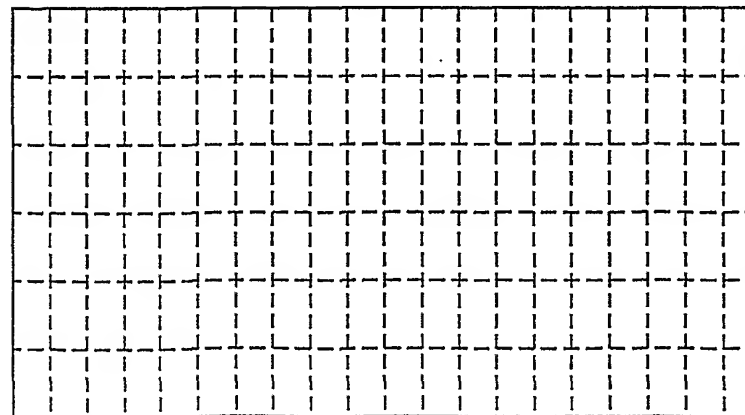


Figure 3D

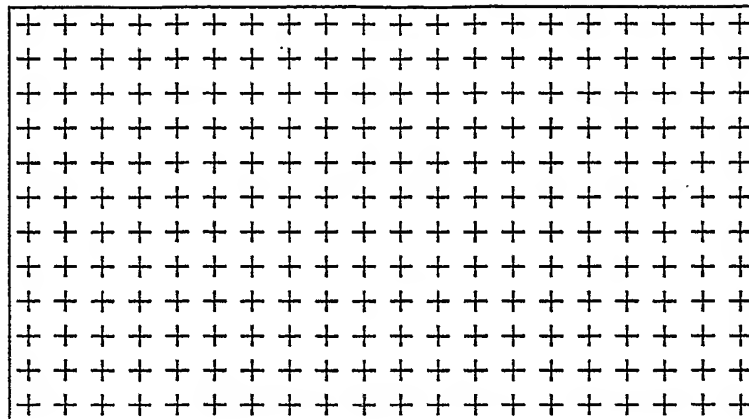


Figure 3E

